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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,053	07/15/2003	Peter G. Bakhit	17566 (AP)	8806

51957 7590 05/27/2005

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,053	BAKHIT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2005 and 28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54 and 56-61* is/are rejected.

7)☒ Claim(s) *55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20050207*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 57 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 57 is dependent upon canceled claim 11, and claim 59 is dependent upon canceled claim 20.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 54, 56, and 58 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585) in view of Saettone et al (U.S. Patent No. 6,056,950). Thim et al teach pharmaceutical compositions comprising TFF2 peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can be used to treat dry eyes. The compositions can comprise buffering agents. See, e.g., paragraphs [0051], [0077] - [0083], [0133], [0173], and claims 8, 21-23, 30, and 49. Thim et al teach their compositions in the form of eye droplets for the treatment of dry eye (see, e.g., claims 22 and 23), but do not teach the presence of tamarind seed polysaccharide in the eye droplets. Saettone et al teach the inclusion of tamarind seed polysaccharide in artificial tears for the treatment of dry eye. The inclusion of tamarind seed polysaccharide results in prolonging the permanence time of active agents introduced by the eye in the artificial tears. Other agents to be included in the compositions are buffers, preservatives, and antimicrobial agents. See, e.g., the Abstract and column 8, lines 8-16. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the tamarind seed polysaccharide of Saettone et al in the eye droplets of Thim et al because the tamarind seed polysaccharide would have been expected to cause an increase in the duration of action of the TFF2 peptides of Thim et

al. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include buffers, preservatives, and antimicrobial agents in the compositions of Thim et al as modified above by Saettone et al because Thim et al and Saettone et al teach that these components are known to be used in compositions for treating dry eye, and their inclusion with only the expected gain in function would have been prima facie obvious. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pHs for the buffered compositions of Thim et al as modified above by Saettone et al because pH is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

4. Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585) in view of Saettone et al (U.S. Patent No. 6,056,950) as applied against claims 54, 56, and 58 above, and further in view of Kaswan (U.S. Patent No. 4,839,342). Thim et al and Saettone et al do not teach including another therapeutically active agent such as cyclosporin A in their compositions for treating dry eye. Kaswan teaches the administration of cyclosporin A in concentrations of 0.01 to 50 wt.% to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 21-57). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the active agents of Kaswan in the compositions of Thim et al as modified above by Saettone et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause. It

would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal cyclosporin A concentrations for the compositions of Thim et al as modified above by Saettone et al and Kaswan because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

5. Claim 60 is rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0032585) in view of Kaswan (U.S. Patent No. 4,839,342). Thim et al teach pharmaceutical compositions comprising TFF2 peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can be used to treat dry eyes. See, e.g., paragraphs [0051], [0077] - [0083], [0133], [0173], and claims 8, 21-23, 30, and 49. Thim et al do not teach including another therapeutically active agent such as cyclosporin A. Kaswan teaches the administration of cyclosporin A in concentrations of 0.01 to 50 wt.% to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 21-57). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the active agents of Kaswan in the compositions of Thim et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal cyclosporin A concentrations for the compositions of Thim et

al as modified above by Kaswan because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

6. Claims 54, 56, and 58 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496) in view of Saettone et al (U.S. Patent No. 6,056,950). Thim et al teach pharmaceutical compositions comprising TFF1 and TFF3 dimer peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can comprise buffering agents. The compositions can be used to treat dry eyes. See, e.g., paragraphs [0074] - [0076], [0117], and claims 6-8, 22, 23, 33, 34, and 39. Thim et al teach their compositions in the form of eye droplets for the treatment of dry eye (see, e.g., claims 22 and 23), but do not teach the presence of tamarind seed polysaccharide in the eye droplets. Saettone et al teach the inclusion of tamarind seed polysaccharide in artificial tears for the treatment of dry eye. The inclusion of tamarind seed polysaccharide results in prolonging the permanence time of active agents introduced by the eye in the artificial tears. Other agents to be included in the compositions are buffers, preservatives, and antimicrobial agents. See, e.g., the Abstract and column 8, lines 8-16. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the tamarind seed polysaccharide of Saettone et al in the eye droplets of Thim et al because the tamarind seed polysaccharide would have been expected to cause an increase in the duration of action of the TFF2 peptides of Thim et al. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include buffers, preservatives, and antimicrobial agents in the compositions of Thim et al as modified above by Saettone et al because Thim et al and Saettone et al teach that these components are known to be used in compositions for treating dry eye, and

their inclusion with only the expected gain in function would have been prima facie obvious. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal pHs for the buffered compositions of Thim et al as modified above by Saettone et al because pH is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

7. Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496) in view of Saettone et al (U.S. Patent No. 6,056,950) as applied against claims 54, 56, and 58 above, and further in view of Kaswan (U.S. Patent No. 4,839,342). Thim et al and Saettone et al do not teach including another therapeutically active agent such as cyclosporin A in their compositions for treating dry eye. Kaswan teaches the administration of cyclosporin A in concentrations of 0.01 to 50 wt.% to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 21-57). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the active agents of Kaswan in the compositions of Thim et al as modified above by Saettone et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal cyclosporin A concentrations for the compositions of Thim et al as modified above by Saettone et al and Kaswan because concentration is an art-

recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

8. Claim 60 is rejected under 35 U.S.C. 103(a) as being obvious over Thim et al (U.S. Patent Application Publication 2003/0153496) as applied against claims 1, 6, 10, 16, 20, 25, 29-32, and 35-38 above, and further in view of Kaswan (U.S. Patent No. 4,839,342). Thim et al teach pharmaceutical compositions comprising TFF1 and TFF3 dimer peptides. The compositions can be aqueous. The compositions can comprise a mucin glycoprotein. The compositions can be used to treat dry eyes. See, e.g., paragraphs [0074] - [0076], [0117], and claims 6-8, 22, 23, 33, 34, and 39. Thim et al do not teach including another therapeutically active agent such as cyclosporin A with their compositions for treating dry eye. Kaswan teaches the administration of cyclosporin A in concentrations of 0.01 to 50 wt.% to treat dry eye (see, e.g., column 1, lines 8-15, and column 6, lines 21-57). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the active agent of Kaswan in the compositions of Thim et al for the treatment of dry eye because it is prima facie obvious to use a mixture of two materials each of which has been used separately for the same process (In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980)), and because the use of plural active agents would increase the chances that effective treatment would occur by targeting more than one underlying biochemical cause. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal cyclosporin A concentrations for the compositions of Thim et al as modified above by Kaswan because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

9. Applicant's arguments filed February 7, 2005 and April 28, 2005 have been fully considered but they are not persuasive.

The claims rejected over prior art are not limited to the subject matter indicated allowable in the previous Office action, and Applicants have not provided any arguments as to why the new claims should be allowed.

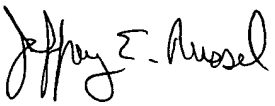
10. Claim 55 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 57 and 59 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 23, 2005